Complete Summary

GUIDELINE TITLE

Nutrition principles and recommendations in diabetes.

BIBLIOGRAPHIC SOURCE(S)

Franz MJ, Bantle JP, Beebe CA, Brunzell JD, Chiasson JL, Garg A, Holzmeister LA, Hoogwerf B, Mayer-Davis E, Mooradian AD, Purnell JQ, Wheeler M. Nutrition principles and recommendations in diabetes. Diabetes Care 2004 Jan; 27 (Suppl 1): S36-46. [7 references] PubMed

COMPLETE SUMMARY CONTENT

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METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS QUALIFYING STATEMENTS

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

- Type 1 diabetes
- Type 2 diabetes
- Gestational diabetes

GUIDELINE CATEGORY

Management Prevention Treatment

CLINICAL SPECIALTY

Endocrinology
Family Practice
Internal Medicine
Nutrition
Obstetrics and Gynecology

Pediatrics Preventive Medicine

INTENDED USERS

Advanced Practice Nurses Dietitians Nurses Physician Assistants Physicians

GUI DELI NE OBJECTI VE (S)

- To provide evidence-based principles and recommendations for diabetes medical nutrition therapy
- To improve diabetes care by increasing the awareness of clinicians and persons with diabetes about beneficial nutrition therapies

TARGET POPULATION

- Adults and children with type 1 diabetes
- Adults and children with type 2 diabetes
- Pregnant and lactating women with diabetes
- Older adults with diabetes
- Individuals treated with insulin or insulin secretagogues
- Individuals at risk for diabetes

INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Medical nutrition therapy
- 2. Limited alcohol intake
- 3. Structured, intensive lifestyle modification programs

MAJOR OUTCOMES CONSIDERED

- Blood glucose levels
- Blood lipid levels
- Blood pressure levels
- Rates of diabetes, macrovascular disease and vascular disease, obesity, dyslipidemia, cardiovascular disease, hypertension, and nephropathy
- Quality of life

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Recommendations have been assigned ratings of A, B or C, depending on the quality of evidence (see table below). Expert opinion (E) is a separate category for recommendations in which there is as yet no evidence from clinical trials, in which clinical trials may be impractical, or in which there is conflicting evidence. Recommendations with an "A" rating are based on large, well-designed clinical trials or well done meta-analyses. Generally, these recommendations have the best chance of improving outcomes when applied to the population to which they are appropriate. Recommendations with lower levels of evidence may be equally important but are not as well supported.

American Diabetes Association's evidence grading system for clinical practice recommendations:

Α

Clear evidence from well-conducted, generalizable, randomized controlled trials that are adequately powered, including:

- Evidence from a well-conducted multicenter trial
- Evidence from a meta-analysis that incorporated quality ratings in the analysis
- Compelling non-experimental evidence, i.e., "all or none" rule developed by the Center for Evidence Based Medicine at Oxford*

Supportive evidence from well-conducted randomized, controlled trials that are adequately powered, including:

- Evidence from a well-conducted trial at one or more institutions
- Evidence from a meta-analysis that incorporated quality ratings in the analysis

*Either all patients died before therapy and at least some survived with therapy, or some patients died without therapy and none died with therapy. Example: use of insulin in the treatment of diabetic ketoacidosis.

В

Supportive evidence from well-conducted cohort studies, including:

- Evidence from a well-conducted prospective cohort study or registry
- Evidence from a well-conducted meta-analysis of cohort studies

Supportive evidence from a well-conducted case-control study

C

Supportive evidence from poorly controlled or uncontrolled studies:

- Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results
- Evidence from observational studies with high potential for bias (such as case series with comparison with historical controls)
- Evidence from case series or case reports

Conflicting evidence with the weight of evidence supporting the recommendation

Ε

Expert consensus or clinical experience

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

These recommendations were peer-reviewed, modified, and approved by the Professional Practice Committee and the Executive Committee, October 2001.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The evidence grading system (A-C, E) is defined at the end of the Major Recommendations field.

Because of the complexity of nutrition issues, it is recommended that a registered dietitian, knowledgeable and skilled in implementing nutrition therapy into diabetes management and education, be the team member providing medical nutrition therapy. However, it is essential that all team members be knowledgeable about nutrition therapy and supportive of the person with diabetes who needs to make lifestyle changes.

<u>Carbohydrate</u>

A-Level Evidence

- Foods containing carbohydrate from whole grains, fruits, vegetables, and lowfat milk are important components and should be included in a healthy diet.
- With regard to the glycemic effects of carbohydrates, the total amount of carbohydrate in meals or snacks is more important than the source or type.
- As sucrose does not increase glycemia to a greater extent than isocaloric amounts of starch, sucrose and sucrose-containing foods do not need to be restricted by people with diabetes; however, they should be substituted for other carbohydrate sources or, if added, be covered with insulin or other glucose-lowering medication.
- Non-nutritive sweeteners are safe when consumed within the acceptable daily intake levels established by the U.S. Food and Drug Administration.

B-Level Evidence

- Individuals receiving intensive insulin therapy should adjust their premeal insulin dosages based on the carbohydrate content of meals.
- Although the use of low-glycemic index foods may reduce postprandial hyperglycemia, there is not sufficient evidence of long-term benefit to recommend use of low-glycemic index diets as a primary strategy in food/meal planning.
- As with the general public, consumption of dietary fiber is to be encouraged; however, there is no reason to recommend that people with diabetes consume a greater amount of fiber than other Americans.

C-Level Evidence

Individuals receiving fixed daily insulin dosages should try to be consistent in day-to-day carbohydrate intake.

Expert Consensus

- Carbohydrate and monounsaturated fat should together provide 60 to 70% of energy intake. However, the metabolic profile and need for weight loss should be considered when determining the monounsaturated fat content of the diet.
- Sucrose and sucrose-containing foods should be eaten in the context of a healthy diet.

<u>Protein</u>

B-Level Evidence

- In persons with controlled type 2 diabetes, ingested protein does not increase plasma glucose concentrations, although protein is just as potent a stimulant of insulin secretion as carbohydrate.
- For persons with diabetes, especially those not in optimal glucose control, the protein requirements may be greater than the U.S. Recommended Dietary Allowance, but not greater than usual intake.

Expert Consensus

- For persons with diabetes, there is no evidence to suggest that usual protein intake (15 to 20% of total daily energy) should be modified if renal function is normal.
- The long-term effects of diets high in protein and low in carbohydrate are unknown. Although such diets may produce short-term weight loss and improved glycemia, it has not been established that weight loss is maintained long-term. The long-term effect of such diets on plasma low-density lipoprotein (LDL) cholesterol is also a concern.

Dietary Fat

A-Level Evidence

- Less than 10% of energy intake should be derived from saturated fats. Some individuals (i.e., persons with LDL cholesterol ≥100 mg/dl) may benefit from lowering saturated fat intake to <7% of energy intake.
- Dietary cholesterol intake should be <300 mg/day. Some individuals (i.e., persons with LDL cholesterol ≥100 mg/dl) may benefit from lowering dietary cholesterol to <200 mg per day.

B-Level Evidence

 To lower LDL cholesterol, energy derived from saturated fat can be reduced if weight loss is desirable or replaced with either carbohydrate or monounsaturated fat when weight loss is not a goal.

- Intake of trans-unsaturated fatty acids should be minimized.
- Reduced-fat diets when maintained long-term contribute to modest loss of weight and improvement in dyslipidemia.
- Two to three servings of fish per week provide dietary n-3 polyunsaturated fat and can be recommended.

C-Level Evidence

Polyunsaturated fat intake should be approximately 10% of energy intake.

Energy Balance and Obesity

A-Level Evidence

- In insulin-resistant individuals, reduced energy intake and modest weight loss improve insulin resistance and glycemia in the short-term.
- Structured programs that emphasize lifestyle changes, including education, reduced fat (<30% of daily energy) and energy intake, regular physical activity, and regular participant contact, can produce long-term weight loss on the order of 5 to 7% of starting weight.
- Exercise and behavior modification are most useful as adjuncts to other weight loss strategies. Exercise is helpful in maintenance of weight loss.
- Standard weight reduction diets, when used alone, are unlikely to produce long-term weight loss. Structured intensive lifestyle programs are necessary.

Micronutrients

B-Level Evidence

- There is no clear evidence of benefit from vitamin or mineral supplementation in people with diabetes who do not have underlying deficiencies. Exceptions include folate for prevention of birth defects and calcium for prevention of bone disease.
- Routine supplementation of the diet with antioxidants is not advised because of uncertainties related to long-term efficacy and safety.

Alcohol

B-Level Evidence

- If individuals choose to drink alcohol, daily intake should be limited to one drink for adult women and two drinks for adult men. One drink is defined as 12 oz of beer, 5 oz of wine, or 1.5 oz of distilled spirits.
- To reduce risk of hypoglycemia, alcohol should be consumed with food.

A discussion of special considerations for type 1 diabetes and type 2 diabetes is presented in the original guideline document.

Children and Adolescents with Diabetes

Expert Consensus

- Individualized food/meal plans and intensive insulin regimens can provide flexibility for children and adolescents with diabetes to accommodate irregular meal times and schedules, varying appetite, and varying activity levels.
- Nutrient requirements for children and adolescents with type 1 or type 2 diabetes appear to be similar to other same age children and adolescents.

Pregnancy and Lactation

Expert Consensus

- Nutrition requirements during pregnancy and lactation are similar for women with and without diabetes.
- Medical nutrition therapy for gestational diabetes focuses on food choices for appropriate weight gain, normoglycemia, and absence of ketones.
- For some women with gestational diabetes, modest energy and carbohydrate restriction may be appropriate.

Older Adults with Diabetes

A-Level Evidence

- Energy requirements for older adults are less than requirements for younger adults.
- Physical activity should be encouraged.

Expert Consensus

In the elderly, undernutrition is more likely than overnutrition, and therefore caution should be exercised when prescribing weight loss diets.

Acute Complications of Diabetes and Comorbid Conditions

<u>Hypoglycemia</u>

A-Level Evidence

Glucose is the preferred treatment for hypoglycemia, although any form of carbohydrate that contains glucose may be used.

B-Level Evidence

- Ingestion of 15 to 20 grams of glucose is an effective treatment, but blood glucose may be only temporarily corrected.
- During acute illnesses, testing blood glucose and blood or urine for ketones, drinking adequate amounts of fluids, and ingesting carbohydrate are important.

Expert Consensus

Initial response to treatment for hypoglycemia should be seen in approximately 10 to 20 minutes; however, blood glucose should be evaluated in approximately 60 minutes, as additional treatment may be necessary.

<u>Hypertension</u>

A-Level Evidence

- In both normotensive and hypertensive individuals, a reduction in sodium intake lowers blood pressure.
- A modest amount of weight loss beneficially affects blood pressure.

Expert consensus

The goal should be to reduce sodium intake to 2,400 mg (100 mmol) or sodium chloride (salt) to 6,000 mg per day.

<u>Dyslipidemia</u>

B-Level Evidence

- For persons with elevated plasma low-density lipoprotein cholesterol, saturated fatty acids and trans-saturated fatty acids should be limited to <10% and perhaps to <7% of energy.
- For individuals with elevated plasma triglycerides, reduced high-density lipoprotein (HDL) cholesterol, and small dense low-density lipoprotein (LDL) cholesterol (the metabolic syndrome), improved glycemic control, modest weight loss, dietary saturated fat restriction, increased physical activity, and incorporation of monounsaturated fats may be beneficial.

Expert Consensus

Energy derived from saturated fat can be reduced if weight loss is desirable or replaced with either carbohydrates or monounsaturated fats if weight loss is not a goal.

Nephropathy

C-Level Evidence

In individuals with microalbuminuria, reduction of protein to 0.8 to 1.0 g/kg body weight per day and in individuals with overt nephropathy, reduction to 0.8 g/kg body weight per day, may slow the progression of nephropathy.

Catabolic Illness

Expert Consensus

• The energy needs of most hospitalized patients can be met by providing 25 to 35 kcal/kg body weight.

• Protein needs are between 1.0 and 1.5 g/kg body weight, the higher end of the range being for more stressed patients.

Diabetes Prevention

A-Level Evidence

Structured programs that emphasize lifestyle changes, including education, reduced fat and energy intake, regular physical activity, and regular participant contact, can produce long-term weight loss of 5 to 7% of starting weight and reduce the risk for developing diabetes.

B-Level Evidence

All individuals, especially family members of persons with type 2 diabetes, should be encouraged to engage in regular physical activity to decrease risk of developing type 2 diabetes.

Definitions:

American Diabetes Association's evidence grading system for clinical practice recommendations:

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Clear evidence from well-conducted, generalizable, randomized controlled trials that are adequately powered, including:

- Evidence from a well-conducted multicenter trial
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- Evidence from observational studies with high potential for bias (such as case series with comparison with historical controls)
- Evidence from case series or case reports

Conflicting evidence with the weight of evidence supporting the recommendation

F

Expert consensus or clinical experience

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The evidence is from randomized, controlled trials; cohort and case-controlled studies; and observational studies.

The type of supporting evidence is identified and graded for the recommendations (see the "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Goals of medical nutrition therapy that apply to all persons with diabetes are:

- Attain and maintain optimal metabolic outcomes, including:
 - Blood glucose levels in the normal range or as close to normal as is safely possible to prevent or reduce the risk for complications of diabetes
 - A lipid and lipoprotein profile that reduces the risk for macrovascular disease
 - Blood pressure levels that reduce the risk for vascular disease

- Prevent and treat the chronic complications of diabetes. Modify nutrient intake and lifestyle as appropriate for the prevention and treatment of obesity, dyslipidemia, cardiovascular disease, hypertension, and nephropathy.
- Improve health through healthy food choices and physical activity.
- Address individual nutritional needs taking into consideration personal and cultural preferences and lifestyle while respecting the individual's wishes and willingness to change.

Goals of medical nutrition therapy that apply to specific situations include the following:

- For youth with type 1 diabetes, to provide adequate energy to ensure normal growth and development, integrate insulin regimens into usual eating and physical activity habits
- For youth with type 2 diabetes, to facilitate changes in eating and physical activity habits that reduce insulin resistance and improve metabolic status
- For pregnant and lactating women, to provide adequate energy and nutrients needed for optimal outcomes
- For older adults, to provide for the nutritional and psychosocial needs of an aging individual
- For individuals treated with insulin or insulin secretagogues, to provide selfmanagement education for treatment (and prevention) of hypoglycemia, acute illnesses, and exercise-related blood glucose problems
- For individuals at risk for diabetes, to decrease risk by encouraging physical activity and promoting food choices that facilitate moderate weight loss or at least prevent weight gain

POTENTIAL HARMS

- It is noteworthy that there are no health concerns with folate supplementation, except for aggravating vitamin B12 deficiency and occasionally causing seizures in people with epilepsy and marginal folate status who are receiving anticonvulsants.
- In older adults, because of the potential risks of exercise (cardiac ischemia, musculoskeletal and foot injuries, and hypoglycemia in patients treated with insulin or insulin secretagogues), an evaluation and education session should be undertaken before initiating an exercise training program.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

• Evidence is only one component of clinical decision-making. Clinicians care for patients, not populations; guidelines must always be interpreted with the needs of the individual patient in mind. Individual circumstances, such as comorbid and coexisting diseases, age, education, disability, and above all, patient's values and preferences, must also be considered and may lead to different treatment targets and strategies. Also, conventional evidence hierarchies, such as the one adapted by American Diabetes Association, may miss some nuances that are important in diabetes care.

• Historically, nutrition recommendations for diabetes and related complications were based on scientific knowledge, clinical experience, and expert consensus; however, it was often difficult to discern the level of evidence used to construct the recommendations. To address this problem, the 2002 technical review (see the "Companion Documents" field) and this position statement provide principles and recommendations classified according to the level of evidence available using the American Diabetes Association evidence grading system. However, the best available evidence must still take into account individual circumstances, preferences, and cultural and ethnic preferences, and the person with diabetes should be involved in the decision-making process.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Franz MJ, Bantle JP, Beebe CA, Brunzell JD, Chiasson JL, Garg A, Holzmeister LA, Hoogwerf B, Mayer-Davis E, Mooradian AD, Purnell JQ, Wheeler M. Nutrition principles and recommendations in diabetes. Diabetes Care 2004 Jan; 27 (Suppl 1): S36-46. [7 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001 Oct (republished 2004 Jan)

GUIDELINE DEVELOPER(S)

American Diabetes Association - Professional Association

SOURCE(S) OF FUNDING

The American Diabetes Association (ADA) received an unrestricted educational grant from LifeScan, Inc., a Johnson and Johnson Company, to support publication of the 2004 Diabetes Care Supplement.

GUI DELI NE COMMITTEE

Professional Practice Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Authors of Position Statement, Initial Draft: Marion J. Franz, MS, RD, CDE (cochair), John P. Bantle, MD (co-chair); Christine A. Beebe, MS, RD, CDE; John D. Brunzell, MD; Jean-Louis Chiasson, MD; Abhimanyu Garg, MD; Lea Ann Holzmeister, RD, CDE; Byron Hoogwerf, MD; Elizabeth Mayer-Davis, PhD, MS, RD; Arshag D. Mooradian, MD; Jonathan Q. Purnell, MD; and Madelyn Wheeler, MS, RD, CDE

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUI DELI NE STATUS

This is the current release of the guideline.

The guideline was originally approved in October 2001.

American Diabetes Association (ADA) position statements are reissued annually.

GUIDELINE AVAILABILITY

Electronic copies: Available from the <u>American Diabetes Association (ADA) Web</u> site.

Print copies: Available from American Diabetes Association, 1701 North Beauregard Street, Alexandria, VA 22311.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

Franz MJ, Bantle JP, Beebe CA, Brunzell JD, Chiasson J-L, Garg A, Holzmeister LA, Hoogwerf B, Mayer-Davis E, Mooradian AD, Purnell JQ, Wheeler M. Evidence-based nutrition principles and recommendations for the treatment and prevention of diabetes and related complications (Technical Review). Diabetes Care 2002:25:148-98.

Electronic copies: Available from the <u>American Diabetes Association (ADA) Website</u>.

Print copies: Available from American Diabetes Association (ADA), 1701 North Beauregard Street, Alexandria, VA 22311.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on May 10, 2002. This summary was updated on July 29, 2003 and March 23, 2004.

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